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Article

Health policy design analysis: foundations for monitoring and evaluation

Análise de desenho das políticas de saúde: subsídios para o monitoramento e avaliação

Análisis del diseño de políticas de salud: aportes para el monitoreo y la evaluación

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Abstract

Objective: To analyze health policies based on policy design theory, identifying elements that enable their monitoring and evaluation. **Methodology:** A descriptive and exploratory study with a quali-quantitative approach examining health policy design regarding monitoring and evaluation elements. The research universe is Consolidation Ordinance No. 2, dated September 28, 2017, and updates until August 2024. Simple frequency analyses and content analysis were performed. The evaluative axis combined elements of competencies, guidelines, objectives, strategic actions, and specific chapters for monitoring and evaluation. **Results:** Of the 50 analyzed policies, 40 (80%) originated from ministerial ordinances; 36% lack explicit monitoring and evaluation elements; in the others, their incorporation predominates as objectives (62%). Responsibility is mainly shared among federal entities (60%). Four main monitoring and evaluation constructs were identified: activity standardization and regulatory focus, present in 48% of policies; systematic monitoring and data quality (54%); evidence-based evaluation (62%); and ex-post evaluation (68%). In 90% of disease-specific policies, all constructs are present. Only 28% of policies incorporate all four constructs simultaneously. Recent policies emphasize ex-post evaluation and evidence-based decision-making. **Conclusion:** The analysis of health policies points to the need for improvement of continuous processes in monitoring and evaluation mechanisms. The importance of periodic review of older

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policies for incorporating evaluative elements and developing specific monitoring and evaluation methodologies is highlighted, considering the particularities of each policy.
Keywords: Health Policy; Health Evaluation; Health Law; Legal Process.

Resumo

Objetivo: Analisar as políticas de saúde a partir do *"policy design"*, identificando elementos que permitem seu monitoramento e avaliação. **Metodologia:** Estudo descritivo e exploratório, quali-quantitativo, sobre o desenho das políticas de saúde quanto aos elementos de monitoramento e avaliação. O universo de pesquisa é a Portaria de Consolidação nº 2, de 28 de setembro de 2017 e atualizações até agosto de 2024. Realizaram-se análises de frequência simples e análise de conteúdo. O eixo avaliativo combinou elementos de competências, diretrizes, objetivos, ações estratégicas e capítulo específico para monitoramento e avaliação. **Resultado:** Das 50 políticas analisadas, 40 (80%) originaram-se de portarias ministeriais; 36% não há elementos explícitos de monitoramento e avaliação; nas demais, predomina sua incorporação como objetivos (62%). A responsabilidade é majoritariamente compartilhada entre entes federativos (60%). Identificaram-se quatro constructos principais de monitoramento e avaliação: padronização de atividades e foco regulatório, presente em 48% das políticas; monitoramento sistemático e qualidade dos dados (54%); avaliação baseada em evidências (62%); e avaliação *ex-post* (68%). Em 90% das políticas de agravos específicos há a presença de todos os constructos. Apenas 28% das políticas incorporam todos os quatro constructos simultaneamente. As políticas recentes enfatizam a avaliação *ex-post* e evidências para tomada de decisão. **Conclusão:** A análise das políticas de saúde aponta para a necessidade de aperfeiçoamento dos processos contínuos dos mecanismos de monitoramento e avaliação. Destaca-se a importância da revisão periódica das políticas mais antigas para incorporação de elementos avaliativos e o desenvolvimento de metodologias específicas de monitoramento e avaliação, considerando as particularidades de cada política.
Palavras-chave: Política de Saúde; Avaliação em Saúde; Direito Sanitário; Processo Legal.

Resumen

Objetivo: Analizar las políticas de salud desde la teoría del *"policy design"*, identificando elementos que permitan su monitoreo y evaluación. **Metodología:** Estudio descriptivo y exploratorio con enfoque cuali-cuantitativo sobre el diseño de las políticas de salud en cuanto a los elementos de monitoreo y evaluación. El universo de investigación es la Ordenanza de Consolidación n° 2, del 28 de septiembre de 2017 y sus actualizaciones hasta agosto de 2024. Se realizaron análisis de frecuencia simple y análisis de contenido. El eje evaluativo combinó elementos de competencias, directrices, objetivos, acciones estratégicas y capítulo específico para monitoreo y evaluación. **Resultados:** De las 50 políticas analizadas, 40 (80%) se originaron de ordenanzas ministeriales; 36% no tienen elementos explícitos de monitoreo y evaluación; en las demás, predomina su incorporación como objetivos (62%). La responsabilidad es mayoritariamente compartida entre entes federativos (60%). Se identificaron cuatro constructos principales de monitoreo y evaluación: estandarización de actividades y enfoque regulatorio, presente en 48% de las políticas; monitoreo sistemático y calidad de datos (54%); evaluación basada en evidencias (62%); y evaluación *ex-post* (68%). En 90% de las políticas de enfermedades específicas hay presencia de todos los constructos. Solo 28% de las políticas incorporan los cuatro constructos simultáneamente. Las políticas recientes enfatizan la evaluación *ex-post* y evidencias para toma de decisiones. **Conclusión:** El análisis de las políticas de salud apunta a la necesidad de perfeccionamiento de los procesos continuos de los mecanismos de monitoreo y evaluación. Se destaca la importancia de la revisión periódica de las políticas más antiguas para incorporación de elementos evaluativos y el desarrollo de metodologías específicas de monitoreo y evaluación, considerando las particularidades de cada política.
Palabras clave: Política de Salud; Evaluación en Salud; Derecho Sanitario; Processo Legal.

Introduction

The development of monitoring and evaluation (M&E) in public health policy reflects a significant evolution in the management and implementation of government interventions. Since the introduction of public policy analysis by Harold Lasswell in 1936[(1)], the field has undergone substantial transformations, with M&E gaining increasing importance over the decades. Initially focused primarily on policy formulation, the M&E process has expanded to encompass the entire public policy cycle, becoming an essential component in ensuring the effectiveness and efficiency of government interventions[(1)].

M&E provides crucial mechanisms for tracking progress, evaluating results and ensuring that the objectives set out in public policies are achieved. M&E not only enables *accountability* and continuous policy improvement, but also serves as a vital mechanism for ensuring that public interventions remain relevant and effective in an ever-changing environment[(2)].

In 2020, the Pan American Health Organization (PAHO)[)(3)] updated the concept of an integrated approach to health and the interrelationship with the Essential Public Health Functions (EPHFs). In this sense, evaluation, policy development, resource allocation and access form the four stages of this approach. Policy development is based on the formulation of public health policies through promotion, prioritization of problems and strategic planning to meet the population's health needs. In this context of policy development, Almeida et al.[(4)] point out that public policies are governed by the principles of Public Law and need to be formally explained in a way that makes it possible for them to be operationalized from an administrative and legal point of view.

In the Brazilian context, Paim et al.[(5)] analyzed the evolution of the Unified Health System (SUS) and highlighted the importance of M&E for its continuous development. The authors argue that strengthening M&E systems is crucial to tackling the persistent challenges facing the SUS, such as inequalities in access to health services and the need to improve the quality of care. This scenario of SUS development is directly related to the legal bases established by the 1988 Federal Constitution.

The 1988 Federal Constitution[(6)] established the legal and institutional bases which, with implicit and explicit mechanisms on M&E, underpin and demand these practices in public administration, including the health sector. Article 37 of the Constitution, in establishing the principles of public administration - legality, impersonality, morality, publicity and efficiency - implicitly requires government actions to be constantly monitored and evaluated. The principle of efficiency, in particular, demands that public resources be used in such a way as to maximize results, which necessarily implies continuous monitoring and evaluation processes. In addition, the principle of publicity is directly related to the need to make information available on the results of public policies, which involves evaluation mechanisms[(7)].

The system of control and oversight established by the Constitution[(6)] also provides a solid basis for evaluating public policies. Articles 70 and 71 state that the accounting, financial, budgetary, operational and patrimonial supervision of the Union and of direct and indirect administration entities shall be exercised by the National Congress, through external control, and by the internal control system of each Branch. The Tribunal de Contas da União (TCU) has the competence to carry out inspections and audits of an accounting, financial, budgetary, operational and patrimonial nature in the administrative units of the Legislative, Executive and Judicial Branches. These provisions create mechanisms that not only allow, but require the systematic monitoring and evaluation of government policies and programs.

The budget cycle established by the Constitution [(6)] in Articles 165 to 169, which includes the Multi-Year Plan, the Budget Guidelines Law and the Annual Budget Law, presupposes a continuous

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process of planning, execution and evaluation. This cycle requires public policies to be formulated with clear objectives, measurable targets and performance indicators, essential elements for effective monitoring and evaluation. In addition, social participation, provided for in various constitutional articles, such as Article 198 which deals with the Unified Health System, also contributes to the evaluation process by allowing civil society to participate in the formulation, implementation and evaluation of public policies.

Constitutional Amendment Nº. 109 of March 15, 2021 added paragraph 16 to Article 37 of the Constitution Federal[(6)], establishing the evaluation of public policies as a duty of the bodies and entities of the Public and the need to disclose the object to be evaluated and the results achieved. Administration Thus, the 1988 Federal Constitution establishes the legal and institutional bases that make the monitoring and evaluation of public policies necessary and inherent to Brazilian public management.

The constitutional institutionalization of public policy evaluation demands not only a theoretical-methodological approach, but also a broader legal understanding of how these policies are structured. In this sense, Bucci[(8)] offers a fundamental contribution to the field by conceiving public policies as complex institutional arrangements, expressed in government action strategies or programs that aim to coordinate the means available to the state and private activities in order to achieve socially relevant and politically determined objectives. For the author, public policies should be understood as institutional arrangements that need to incorporate evaluation and control mechanisms into their very structure, allowing for constant improvement in their implementation and results. The Law and Public Policies approach, proposed by the author, helps to identify and analyze these monitoring and evaluation mechanisms integrated into the legal-institutional design of policies, offering analytical tools to understand how different elements work together to produce measurable results[(9)].

Thus, the 1988 Federal Constitution, with its updates, establishes the legal and institutional bases that make the monitoring and evaluation of public policies necessary and inherent to Brazilian public management. This normative framework, combined with a theoretical understanding of the nature of public policies, calls for a theoretical-methodological approach to understand how these policies are structured and implemented. In this context, the theory of policy design offers a theoretical framework that makes it possible to examine not only the constituent elements of policies, but also how these elements are articulated to produce measurable results.

As point Howlett, Mukherjee and Woo[(10)], policy design represents an approach that has evolved from a perspective focused on isolated instruments to a more integrated view of policy formulation, considering how different tools and mechanisms are combined to achieve specific objectives. In the field of health, this approach has proved relevant to understanding how different elements of M&E are incorporated into policy design, allowing not only to meet constitutional requirements, but also to promote a continuous process of learning and improving government interventions.

As public management practices have advanced, M&E has been incorporated more systematically into evaluations of *ex-ante* and *ex-post* health policies. In evaluation *ex-ante*, the M&E process is planned from the policy's conception, involving the definition of performance indicators, the establishment of targets and timetables, and the identification of data sources for monitoring. As highlighted in the "Guia Prático de Análise Ex Ante"[(11)], this phase is crucial for creating a monitoring system that allows for the continuous follow-up of the implementation and results of the health policy.

On the other hand, in evaluation*ex-post*, the "Guia Prático de Análise Ex Post"[12] recommends that the M&E process be continuous and systematic, including the regular collection of data on key indicators, periodic analysis of policy performance, and the carrying out of impact evaluations when appropriate. This approach allows the results of M&E to be used to inform adjustments and improvements in health policies, promoting a continuous cycle of learning and improvement.

To support this continuous monitoring and evaluation process, the theory of change[11,12] has emerged as a fundamental tool in the planning and evaluation of health policies, providing a logical framework that spells out how an intervention is intended to achieve its objectives. This approach assumes that every public policy incorporates an implicit or explicit theory about how and why a particular intervention should work to solve a specific public problem.

In the context of M&E, the theory of change plays a crucial role, serving as the basis for the development of an effective M&E system. As highlighted in the practical guides to analysis*ex-ante* [11] and *ex-post* [12], the theory of change "makes explicit the causal logic that structures public policy design"[11,12] , providing a clear framework for defining indicators and evaluating results at different stages of health policy implementation. This articulation between the theory of change and public policy not only allows for more robust planning, but also facilitates the early identification of flaws in the causal chain, allowing for adjustments and corrections during implementation.

The monitoring process, when anchored in the theory of change, becomes more focused and efficient, allowing managers to follow not only the execution of planned activities, but also to check whether the immediate results (*outputs)* are being achieved as expected. In evaluation, the theory of change provides an essential frame of reference for interpreting the results observed, enabling a more in-depth and contextualized assessment that goes beyond the simple measurement of indicators, exploring the causal mechanisms that lead to the results observed in health policies[11,12].

In the evolution of M&A practices, the analysis of public policy design has become increasingly important. This approach, as highlighted by Lima, Aguiar and Lui [13] , is dedicated to studying and understanding the logical structure of public policies and their effectiveness. In the specific field of health policies, design analysis offers a tool for understanding how these policies are structured to achieve their objectives and how their performance is measured and evaluated over time. This approach makes it possible to examine how M&E elements are incorporated into the structure of health policies, identifying patterns, innovations and possible gaps in the mechanisms for monitoring and evaluating results.

In the context of this study, the GM/MS Consolidation Ordinance No. 2 of 28 September 2017 stands out as an important milestone in the organization and structuring of the national health policies of the Unified Health System (SUS). This ordinance consolidated various rules on national health policies, providing a comprehensive overview of the guidelines and principles that guide health actions in the country.

Consolidation Ordinance Nº. 2 is part of a set of six Consolidation Ordinances published by the Office of the Minister (GM) of Health in September 2017. The consolidation of norms is provided for in Article 59 of the Federal Constitution[6], in Complementary Law No. 95/1998 [14] and in Decree No. 12002/2024[15]. Consolidation not only organizes existing rules, but also creates space for future rules to be incorporated by amending the consolidation ordinance, without the need to publish a new ordinance for each change[16].

Currently, the Ministry of Health has 12 Consolidation Ordinances, covering different areas and aspects of public health regulation, organized as follows[17] : six rules from the Minister's Office: (a) Consolidation Ordinance GM/MS No. 1/2017 - Rights and Duties, Organization and Functioning

of the SUS; (b) Consolidation Ordinance GM/MS No. 2 /2017 - National Health Policies of the SUS; (c) Consolidation Ordinance GM/MS No. 3 /2017 - SUS Networks; (d) GM/MS Consolidation Ordinance No. 4 /2017 - SUS Systems and Subsystems; (e) GM/MS Consolidation Ordinance No. 5 /2017 - SUS Health Programs, Actions and Services; (f) GM/MS Consolidation Ordinance No. 6 /2017 - Financing and Transfers. In addition to other five Ordinances issued by the Ministry's Secretariats and one Resolution by the CommissionTripartite Interagency : (a) Consolidation Ordinance SE/MS No. 729/2020 - Consolidation of the norms of the Executive Secretariat of the Ministry of Health; (b) Consolidation Ordinance SESAI/MS No. 1/2020 - Consolidation of norms of the Indigenous Health Care Subsystem; (c) Consolidation Ordinance SGTES/MS No. 1/2021- Consolidation of norms on Labor Management and Health Education; (d) Consolidation SAPS/MS nº 1/2021 - Consolidation Ordinance of norms on Primary Health Care; (e) Consolidation Ordinance SAES/MS nº 1/2022 - Consolidation of norms on Specialized Health Care; (f) Consolidation Resolution CIT nº 1/2021 - Consolidation of resolutions of the Commission Tripartite (CITInteragency) of the Unified Health System (SUS).

The aim of this article is to present the results of an analysis of health policies based on the theory of policy design[10], identifying whether they have elements and variables that allow for M&E. This analysis will allow us to understand how the Brazilian public health sector has incorporated monitoring and evaluation practices into its policies, and how these practices can be improved to ensure more effective and efficient interventions.

Methology

This is a descriptive and exploratory study with a approach qualitative and quantitative on the design of health policies in Brazil in terms of M&E elements. The research universe consisted of the 50 health policies listed in the Consolidation Ordinance No. 2 Ministry of Health's of September 28, 2017 and its updates until August 31, 2024, with changes and the incorporation of new policies.

In the quantitative analysis to define the evaluation axis referring to the analysis of the design of health policies elements of were combined, principles, guidelines, objectives, strategic actions, competence, as well as the existence of a specific chapter for monitoring and evaluation of health policies Descriptive analyses were carried out using simple frequencies (percentages) according to the characteristics (variables) studied. The frequencies were analyzed in groups, according to the topography of the health policy chapter and section groupers in Consolidation Ordinance GM/MS Nº. 2 of 2017 its updates until August 31, 2024.

The qualitative methodology used in this study was based on content analysis, following the principles proposed by Bardin[18] . The analysis process was carried out in three main stages. In the phasepre-analysis , a floating reading of the policy documents was carried out, followed by the selection of relevant passages related to M&E. The material exploration stage involved coding the selected excerpts, identifying recurring themes and creating initial categories, called constructs. In content analysis, according to Bardin[18] , constructs are theoretical or abstract concepts developed for a specific scientific purpose. They are elements which, although they cannot be directly observed or measured, are inferred through observable manifestations or indicators present in the content analyzed, allowing for a structured understanding of the object of study. Finally, in the results processing, inference and interpretation phase, the categories were refined and consolidated, the relationships between the identified constructs and the policies were analyzed, and the emerging patterns were interpreted. This process was carried out by coding and led to the emergence of four distinct constructs, each representing a specific facet of monitoring and evaluation practices in the

context of Brazilian health policies.

The database was prepared in an Excel spreadsheet, which allowed for quantitative descriptive analysis. For the qualitative analysis, a spreadsheet was organized with the formation of "nodes" and "edges". The graphical representation of the constructs created with the related policies was done using the softwareGephi[19].

It should be noted that this study uses information in the public domain and is exempt from submission to an ethics committee, in accordance with Resolution No. 510/2016[20] of the National Health Council (CNS).

Results and discussion

The analysis of the health policies in Consolidation Ordinance Nº. 2 revealed significant patterns both in their organizational structure and in the monitoring and evaluation mechanisms. The results are presented in three complementary sections: first, the organization and general characteristics of the health policies are described; then, how monitoring and evaluation are explicitly manifested in the policies is analyzed; finally, the implicit presence of these elements is examined through content analysis, which enabled the identification of fundamental constructs for understanding how M&E practices are incorporated into SUS health policies.

Description of Health Policies

Consolidation Ordinance Nº. 2 establishes in its topography a hierarchical and thematic structure for the organization of 50 health policies, divided into three main chapters. Chapter I, "Health Policies", is subdivided into four sections: (i) General Policies for the Promotion, Protection and Recovery of Health, which includes eight fundamental policies, including the recently incorporated National Policy for Palliative Care; (ii) Policies for Disease Control and Coping with Health Problems, with four specific policies; (iii) Policies aimed at the Health of Population Segments, covering eleven policies aimed at specific groups; and (iv) Policies for the Promotion of Equity in Health, with four policies aimed at specific populations. Chapter II, "Policies for Organizing Health Care", is organized into two sections: (i) General Policies for Organizing Health Care, with eight structuring policies; and (Health ii) Policies for Specific Conditions, with ten policies that emphasize specific health conditions. Finally, Chapter III, "Policies for Organizing the SUS", presents five fundamental policies for managing and organizing the health system.

This distribution of policies between the chapters reveals an important characteristic of the Brazilian health system, which is the predominance of policies aimed at protecting and promoting health (Chapter I) and organizing care (Chapter II). As Lima, Aguiar and point outLui[21] , this configuration demands specific M&E strategies, capable of capturing both the finalistic and organizational aspects of the policies. The organization into specific chapters and sections demonstrates an alignment with what Almeida et al.[4] call "institutional categories of health policies", essential elements for their operationalization from an administrative and legal point of view.

The origin of health policies in terms of the type of regulation (Table 1) and the issuing authority varies, with the majority coming from the Ministry of Health: 40 health policies (80%) originate from a ministerial ordinance of the Ministry of Health (PRT MS/GM); three (6%) of the health policies were produced by law; two (4%) produced by decrees; two (4%) by resolution of the National Health Council; one (2%) by approval at a conference of the National Health Council; one (2%) by agreement at the CIT; and one (2%) by inter-ministerial ordinance.

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Chart 1. Health policies that are not the result of a ministerial order from the Ministry of Health and the origin of the rules, from 1995 to August 2024.

Health policy	Origin of the standard
National Policy on Science, Technology and Innovation in Health, approved at the 2nd National Conference on Science, Technology and Innovation in Health, held in 2004, and at the 147th Ordinary Meeting of the National Health Council, held on October 6 and 7, 2004;	Approval at CNS Conference
National Policy on Medicinal Plants and Herbal Medicines, established by Decree No. 5,813 of June 22, 2006;	Decree
National Policy for the Homeless, established by Decree No. 7,053 of December 23, 2009;	Decree
National Policy on Blood, Blood Components and Blood Products, established by Law No. 10.205 of March 21, 2001;	Decree
Mental Health Policy, instituted by Law No. 10.216, of April 6, 2001;	Law
Health Care Policy for People with Autism Spectrum Disorders within the scope of the National Policy for the Protection of the Rights of People with Autism Spectrum Disorders, established by Law No. 12,764 of December 27, 2012;	Law
National Oral Health Policy (Smiling Brazil), established by agreement of the Commission Tripartite (CIT) on February 12, 2004;Interagency	CIT agreement
National Policy for Comprehensive Health Care for Persons Deprived of Liberty in the Prison System within the SUS (PNAISP), established by Interministerial Ordinance MS-MJ No. 1 of January 2, 2014;	Interministerial Order
National Health Surveillance Policy, established by Resolution No. 588/2018 of the National Health Council (CNS);	CNS Resolution
National Pharmaceutical Assistance Policy (PNAF), established by CNS Resolution No. 338 of May 6, 2004;	CNS Resolution

Source: Own elaboration.

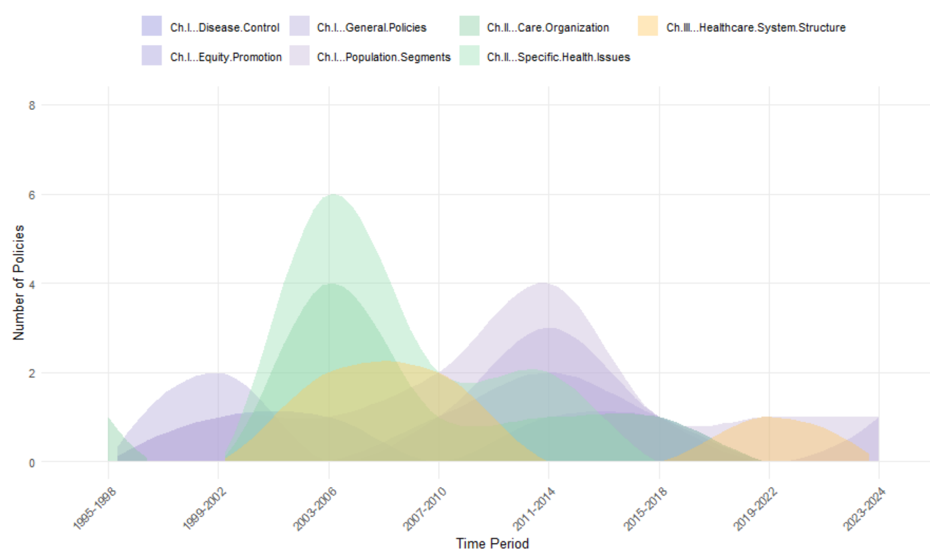
The predominance of ministerial ordinances (80%) as the main normative instrument is in line with what Lima et al.[22] point out in their study on government planning, in which the Ministry of Health is central in conducting sectoral policy, and the presence of policies instituted by different instruments (laws, decrees, resolutions) shows what Almeida et al[4] identified as a process of diversification of the mechanisms for institutionalizing health policies.

The distribution of policies by the variables analyzed in sections and chapters (Table 1) shows that the time frame begins with the date of the first policy found. The temporal analysis reveals three periods of greater normative production: the first, between 2003-2006, is characterized by the concentration of Chapter II policies, with a significant emphasis on the section on care for specific problems (health policies) and the organization of health care (six four policies) (Graph 1). The concentration of Chapter II policies in the 2003-2006 period is in line with what Machado, Lima and Baptista[23] identified in their analysis of the implementation of health policies in Brazil. According to the authors, this period was characterized by the search to structure services and define care models, which reflected in the need for M&E.

The second significant period, 2007-2010, shows a more balanced distribution between the chapters, with normative production distributed between policies aimed at population segments, specific diseases and the organization of the SUS. The third significant period, 2011-2014, stands out for the predominance of Chapter I policies, especially those aimed at population segments (four policies) and general policies for health promotion, protection and recovery (policiesthree).

From 2015 onwards, there was a gradual reduction in the production of new policies. This temporal distribution not only reveals different emphases in the health policy agenda, but also suggests an evolution in the system's maturity, starting from an initial period that emphasizes structuring (organization policies and specific diseases), passing through a phase of expanding access (policies for population segments), until reaching a period of consolidation and refinement of existing policies. The volume and diversity of policies identified reinforces what Almeida et al. [4] showed in their analysis of the institutional categories of health policies in Brazil, which was an intense production of regulations from the 1990s onwards, reflecting the process of consolidating the SUS. This characteristic poses specific challenges for monitoring and evaluation, as Tamaki et al. point out[24] in their study on M&E methodologies in the SUS, especially with regard to the need for instruments that allow policies with different degrees of complexity and institutional maturity to be evaluated.

Graph 1. Distribution of health policies, according to the topography of Consolidation Ordinance Nº. 2, from 1995 to 2024.



Source: Own elaboration.

With regard to the way in which the text is set out in the form of a legal instrument, four (8%) of the health policies included in Consolidation No. 2 are not described in the ordinance, as Ordinance they are articulated in the form of texts and books published on websites; one (2%) policy, which is established by law, is not described in the ordinance; other 47 policies are articulated the in the Consolidation , but the articulation is presented in different ways. For 28 (56%) of the health policies presented in the Consolidation Ordinance, the policy text is incorporated and described in the standard; and Ordinancetwo (4%) are present in the standard, but only in text form. The other health policies are presented in a hybrid form, with 12 (24%) health policies partly described in the standard and partly present in the standard in text form, and three (6%) health policies described in the standard and in other external documents.

The existence of health policies not described in the text of Consolidation Ordinance No. 2 has important legal implications. As pointed out by Almeida et al.[4] in their analysis of the institutional categories of health policies, the way in which policies are defined directly affects their capacity for legal binding and mandatory compliance. According to the authors, policies that are only found in texts and books, without formal incorporation into the norm, may face weaknesses in their

implementation and control. This issue has also been addressed by Aith[25] who points out that the absence of adequate normative formalization can compromise both the administrative enforceability and judicial control of policies and that policies not incorporated into the normative text can have their binding force questioned, hindering processes of responsibility and accountability. Dallari et al.[26] reinforce that the legal certainty of state interventions depends on their adequate normative formalization and that the dispersion of policy content in different types of documents can generate legal uncertainty and hinder social and institutional control.

Explicit monitoring and evaluation in health policies.

The M&E of health policies is presented in ways differentwithin Consolidation Ordinance No. 2. M&E does not appear explicitly in 18 (36%) health policies and in 11 (22%) health policies M&E appears in more than one analyzed category. In the policies that explicitly present M&E, in 31 (62%) health policies it is presented in the form of objectives in the body of the text; 14 (28%) present M&E as a guideline; and in 12 (24%) policies M&E appears as an operational component of the health policy. The absence of explicit M&E in 36% of the policies runs counter to the requirements brought in by EC 109/2021, where the constitutionalization of M&E establishes that it is mandatory, requiring a review of policies that do not include these mechanisms.

The right to health, as a fundamental right, requires not only the formulation of public policies, but also mechanisms to ensure their effectiveness. In this sense, M&E becomes an essential tool for verifying whether policies are in fact promoting universal and equal access to health actions and services, as advocated by Article 196 of the Federal Constitution[25] . Dallari et al.[26] emphasize that the absence or weakness of M&E mechanisms hinders the judicial defense of public policies, since the state is unable to adequately demonstrate the rationality and effectiveness of its allocative choices, while robust M&E results can strengthen the legal certainty of policies and qualify the judicial debate on the right to health.

In 14 (28%) health policies, there is no definition of the competence to carry out M&E. In the policies that do define competence, in 30 (60%) the competence to carry out M&E is the responsibility of the three entities, i.e. the Ministry of Health, the State Health Secretariats and the Health Municipal . In 12 (24%) health policies, M&E is the responsibility of a collegiate body, and in Secretariatseight (16%) health policies, M&E is the responsibility of both the entities and the collegiate body. The fact that in 28% of the policies there is no definition of competence represents a gap and that, according to Almeida et al[4] , the clear definition of responsibilities is essential for the effective implementation of monitoring and evaluation mechanisms.

The shared attribution of M&E competencies between the federative entities, although aligned with the cooperative model of the SUS, presents significant challenges for its implementation. According to Machado, Lima and Baptista[23], federative coordination in the M&E of health policies faces obstacles related to the different technical and administrative capacities of the entities, asymmetries in resources and the complexity of arrangementsinter-federative. Santos and Giovanella[27] point out that there is fragmentation of information systems and heterogeneity of indicators between municipalities and states, and this issue is particularly relevant considering that
30 policies (60%) assign M&E responsibilities to the three federative entities, without, however, specifying coordination and integration mechanisms. Viana et al.[28] also corroborate that there are significant disparities between states and municipalities in terms of the availability of qualified human resources, technological infrastructure and management tools needed to conduct systematic processes M&E.

Table 1. Distribution of health policies in Consolidation Ordinance No. 2 of 2017 (between 1995 and August 2024).

	Chapter I - Health policies					**Chapter II - Health care organization policies**			**Chapter III – SUS organizational policies**	**Total**
	Section I - General Policies for Health Promotion, Protection and Recovery	Section II - Policies to Control Diseases and Combat Health Problems	Section III - Health Policies for Population Segments	Section IV - Health Equity Promotion Policies	**Subtotal**	Section I - General Policies for the Organization of Health Care	Section II - Policies for Attention to Specific Diseases	**Subtotal**		
Period of publication										
1995-1998	-	-	-	-	-	1	-	**1**	-	**1**
1999-2002	2	1	1	-	**4**	-	-	-	-	**4**
2003-2006	-	1	1	-	**2**	4	6	**10**	**2**	**14**
2007-2010	1		2	1	**4**	1	2	**3**	**2**	**9**
2011-2014	3	1	4	2	**10**	1	2	**3**	-	**13**
2015-2018	1	1	1	1	**4**	1	-	**1**	-	**5**
2019-2022	-	-	1	-	**1**	-	-	-	**1**	**2**
2023-2024	1	-	1	-	**2**	-	-	-	-	**2**
Positivization of politics in the norm										
Described in another document	-	-	2	-	**2**	1	-	**1**	**1**	**4**
Described in text in the standard	-	1	1	-	**2**	-	-	-	**-**	**2**
Described in the standard	4	2	4	2	**12**	4	10	**14**	**2**	**28**
Described in the standard and in another document	2	1	-	-	**3**	-	-	-	**-**	**3**
Described in the standard and in text in the standard	1	-	4	2	**7**	3	-	**3**	**2**	**12**
By law and not described in the PCT	1	-	-	-	**1**	-	-	-	**-**	**1**
Presence of explicit M&E in the standard										
No explicit M&E	2	1	2		**5**	3	9	**12**	**1**	**18**

Presents M&A in one category	3	2	6	2	**13**	3	1	**4**	**2**	**19**
It presents M&A in two categories	3		2	2	**7**	2		**2**	**2**	**11**
It presents M&A in three categories		1	1		**2**			**0**	**-**	**2**
M&E description site										
Principle	1	1	-	-	**2**	1	-	**1**	-	**3**
Guidelines	1	2	3	2	**8**	3	1	**4**	**2**	**14**
Objective	2	-	2	4	**8**	8	10	**18**	**5**	**31**
Operational axis Action Organizational strategy Component	3	-	2	2	**7**	2	1	**3**	**2**	**12**
Specific chapter on M&A	2	1	6	-	**9**	3	-	**3**	**2**	**14**
Definition of M&A competence										
Does not define competence	2	3	3		**8**	2	3	**5**	**1**	**14**
It defines the following as its sole competence	4	1	8	2	**15**	5	6	**11**	**2**	**28**
Define shared competence	2			2	**4**	1	1	**2**	**2**	**8**
M&A competence										
Common competence	5	1	6	4	**16**	4	6	**10**	**4**	**30**
Advisory body / CTA	3	-	2	2	**7**	2	1	**3**	**2**	**12**
Specific competence	-	-	-	-	**-**	1	1	**2**	**-**	**2**

Source: Own elaboration.

Monitoring and evaluation implicit in health policies

In the phasepre-analysis , a floating reading of the documents made it possible to identify, as recording units, all the passages that referred to M&E in the policies analyzed and, in the stage of exploring the material, these recording units were subsequently grouped into six thematic axes (Chart 2). The list of acronyms used and the names of the corresponding policies are listed in Annex 1.

Chart 2. Formation of thematic axes and examples of units of analysis.

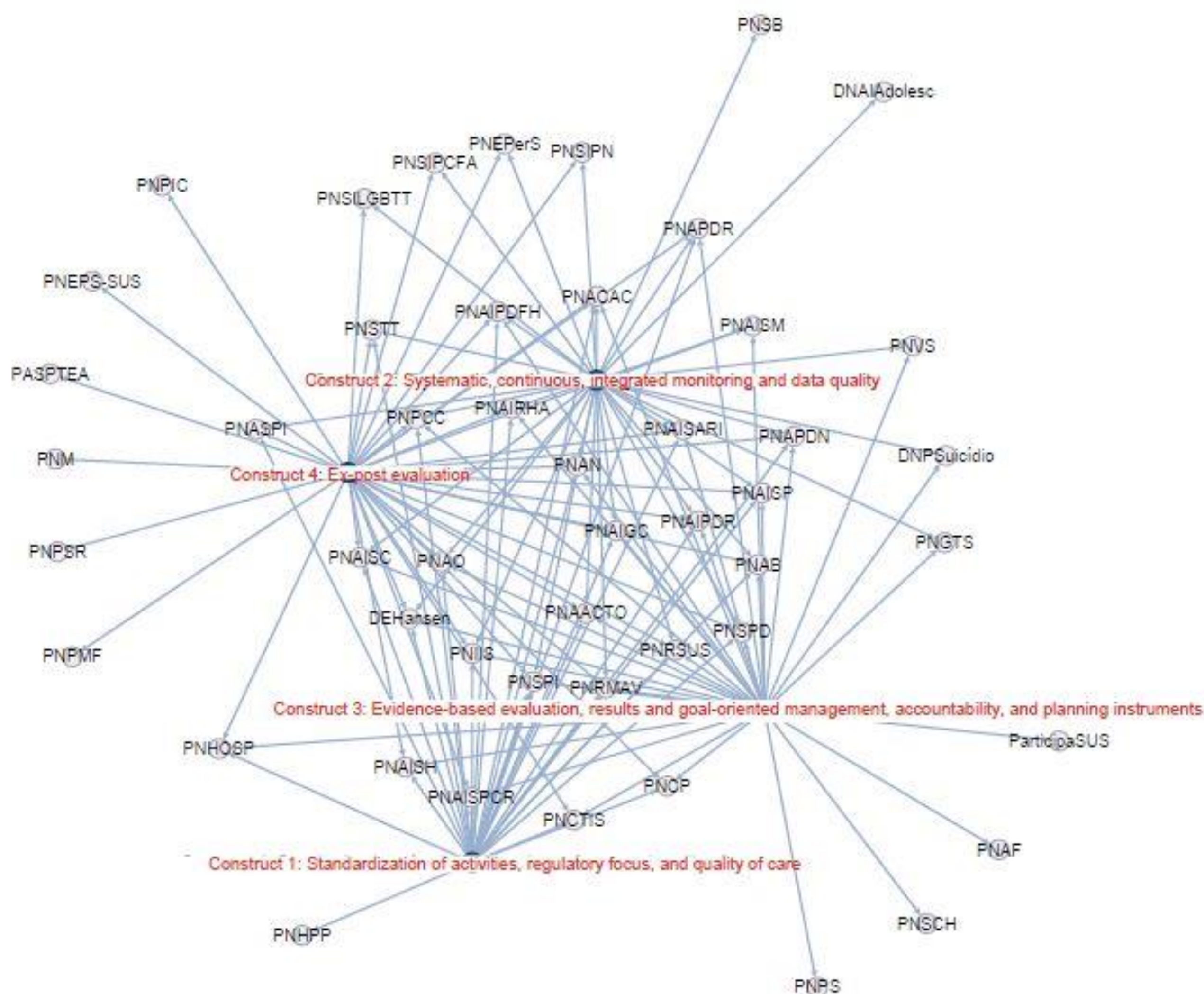
Thematic axis	Examples of the recording units identified
1) Normative and regulatory aspects:	PNHOSP: "establish quality standards for access to and evaluation of hospital services"
	National Blood Policy: "define quality control and assurance requirements"
	PNAB: "establish mechanisms for control, regulation and systematic monitoring"
	National Cardiovascular Care Policy: "standardize high-complexity procedures"
	PNAO: "establish minimum technical criteria"
2) Follow-up and monitoring processes:	PNVS: "develop continuous and systematic monitoring process"
	PNPS: "monitoring and evaluating the development of actions"
	PNAISP: "monitoring and evaluating the development of actions"
	PNAISM: "monitoring the implementation of strategies"
	National Health Policy for the Elderly: "monitoring specific indicators"
3) Evaluation mechanisms:	PNAB: "evaluating the quality of primary care actions"
	PNM: "evaluate the incorporation and impact of new technologies"
	PNVS: "evaluate the impact of the actions taken"
	PNPIC: "evaluate practices and their operating conditions"
	PNSIPCFA: "evaluating people's access to actions and services"
4) Management and planning tools:	PNHOSP: "develop planning and management tools"
	PNIIS: "establish evaluation and control systems"
	PNEPS: "implement information and management systems"
	National Policy for Cancer Prevention and Control: "develop performance evaluation mechanisms"
	PNAISC: "establish instruments for monitoring and evaluating care"
5) Responsibilities and competencies:	PNVS: "coordinating the monitoring process"
	PNPS: "coordinating the implementation of actions with the states"
	PNPS: "articular com os estados a implementação das ações"
	National Mental Health Policy: "define management and evaluation mechanisms"
	PNAISP: "establish criteria and monitoring mechanisms"
6) Information systems and indicators:	PNIIS: "ensuring the interoperability of systems"
	PNVS: "producing qualified information"
	PNM: "develop information system for monitoring"
	PNAB: "develop technical mechanisms and qualification strategies"
	National Regulation Policy: "establish evaluation and monitoring indicators"

Source: Own elaboration.

The analysis of the relationships between these six thematic axes made it possible to identify broader patterns that were consolidated into four main constructs (Figure 1): standardization of activities, regulatory focus and quality of care (bringing together elements from axes 1 and part of 4); systematic, continuous, integrated monitoring and data quality (bringing together elements from axes 2 and 6); evidence-based evaluation, results- and target-oriented management, *accountability* and planning instruments (bringing together elements from axes 3, 4 and 5); and evaluation ,*ex-post* (derived mainly from axis 3 with elements from axis 4).

The systematization of the thematic axes into four main constructs reveals the complexity of M&E mechanisms in health policies and this process is also discussed by Lima, Aguiar and Lui[21] where they mention the importance of examining how different elements come together to produce more or less robust arrangements for achieving the proposed objectives.

Figure 1. Relationship between health policies and monitoring and evaluation constructs.



Source: Prepared by the authors using softwareGephi.

The first construct, characterized by the standardization of activities, regulatory focus and quality of care, is present in 48% of the policies analyzed. This construct emphasizes normative and regulatory

aspects, with an emphasis on standardizing processes and services, establishing quality criteria and parameters, and clearly defining procedures and protocols. Its presence is more significant in high-complexity and specialized care policies, as shown in the excerpts:

> [...] establish quality standards for access to and evaluation of hospital services (PNHOSP)

> [...] define requirements for the control and quality assurance of services and products (National Blood Policy)

> [...] establish minimum technical criteria for the organization and operation of services (PNAO)

The second construct, present in 54% of the policies, highlights systematic, continuous and integrated monitoring and data quality. This construct emphasizes the continuous monitoring of actions, integration between different information systems and shows special concern for the quality and reliability of data, including the definition of specific indicators. Lima, Aguiar and Lui[21] emphasize that the ability to produce and analyse data continuously and reliably is a necessary condition for qualifying the decision-making process and promoting adjustments to policies when necessary. There is a complementarity between this construct and evidence-based evaluation, suggesting an important complementarity between these dimensions, as shown in the excerpts:

> [...] develop a continuous and systematic process for monitoring health indicators (PNVS)

> [...] monitor and evaluate the development of actions on an ongoing and systematic basis (PNPS)

> [...] monitor specific indicators for the elderly population systematically and continuously (National Health Policy for the Elderly)

The third construct, identified in 62% of the policies, focuses on evidence-based evaluation, results- and target-oriented management, *accountability* and planning instruments. This construct is characterized by an emphasis on measurable results, the use of evidence for decision-making, the incorporation of accountability mechanisms and integration with planning instruments. The aspects highlighted in this third construct are in line with EC 109/2021, which establishes not only the mandatory nature of M&E, but also its link to the budget process, reinforcing the importance of evidence-based evaluation. This construct is more frequent in recent policies or those that have been updated, as shown in the excerpts:

> [...] assess the incorporation and impact of new technologies based on scientific evidence (PNM)

> [...] develop performance evaluation mechanisms based on indicators (National Policy for Cancer Prevention and Control)

> [...] implement information and management systems to monitor results (PNEPS)

Finally, the fourth construct, related to evaluationex-post , is present in 68% of the policies analyzed. This construct emphasizes evaluation after the policies have been implemented, including analysis of impacts and results, verification that the proposed objectives have been achieved and organizational learning. It is important to note that, although it is the most frequent construct, it often appears in isolation in the policies, suggesting a possible disarticulation with other M&E elements, as can be seen in the excerpts:

> [...] evaluate the impact of the actions taken on the health situation of the population (PNVS)
>
> [...] evaluate practices and their operating conditions, as well as their results and impacts PNPIC)
>
> [...] evaluate the population's access to the health actions and services implemented (PNSIPCFA)

It is worth noting that the Mental Health Policy was not included in any M&E construct. The policy is established by Law No. 10.216/2001 and in Consolidation Ordinance No. 2 there are only the Regulations that deal with the institution and composition of the National Collegiate of Mental Health Coordinators and the National Forum on Child and Youth Mental Health. Although the law represents a milestone in the protection of the rights of people with mental disorders and the policy establishes collegiate bodies, no monitoring and evaluation mechanisms have been identified.

Analysis by policy category revealed specific patterns. In Chapter I, General Health Promotion, Protection and Recovery Policies showed less incorporation of Construct 1 (37.5%) and greater presence of Construct 3 (62.5%), suggesting an emphasis on evaluating results to the detriment of standardizing processes. Disease Control Policies showed consistency in Constructs 2 and 3 (100% in both), but total absence of Construct 1. Policies aimed at the Health of Population Segments and Policies to Promote Equity showed strong presence of Constructs 2, 3 and 4, with evaluation ex-post present in all policies in this category.

In Chapter II, the General Policies for the Organization of Health Care showed a high degree of incorporation of Construct 1 (87.5%), but less of Construct 2 (25%), indicating an emphasis on regulatory aspects to the detriment of systematic monitoring. On the other hand, Policies for Specific Health Conditions showed the highest degree of incorporation of the M&E constructs, with 90% of the policies covering all four constructs, suggesting a more comprehensive and systematized approach to monitoring and evaluation in this category.

In Chapter III, referring to SUS Organization Policies, there was a significant presence of Constructs 1 and 3 (60% in both), with variation in the incorporation of the other constructs. evaluation Ex-post (Construct 4) was identified in 60% of the policies in this category.

As for the integration of the constructs in the policies analyzed, it was found that 14 policies (28%) incorporate all four constructs, 17 policies (34%) have three constructs, 11 policies (22%) include two constructs and eight policies (16%) have only one construct. This distribution suggests different levels of maturity in the development of M&E mechanisms among the policies analyzed.

The temporal analysis, considering policy updates, indicates a trend towards greater incorporation of M&E constructs in more recent policies, with particular emphasis on evaluationex-post .

Specific patterns were also identified in the different policy categories. Policies aimed at specific diseases and highly complex conditions showed greater maturity in M&E mechanisms, while policies to promote equity, although consistent in the incorporation of Constructs 2, 3 and 4, showed less presence of standardization and regulation elements (Construct 1).

The analyses revealed important gaps in the incorporation of M&E constructs in certain policy categories. In policies to promote equity, there was a systematic absence of Construct 1, indicating a possible need to strengthen regulatory aspects and standardization in these policies. Organizational policies, on the other hand, showed significant variability in the incorporation of systematic monitoring (Construct 2), suggesting opportunities for improvement in continuous monitoring mechanisms.

As for the evolution of the maturity of M&E mechanisms, a progressive movement towards greater completeness of the constructs was identified in the most recent or updated policies. This trend is particularly evident in the strengthening of evaluation ex-post (Construct 4) and the growing emphasis on evidence and results (Construct 3), indicating a possible influence of contemporary evidence-based public management practices.

Conclusion

The analysis of health policies allowed us to identify important characteristics of M&E in the SUS. The results showed that 36% of the policies do not have explicit M&E elements, while in the others there is a predominance of their incorporation as objectives (62%). Responsibility for M&E is mostly shared between federal entities (60%), although 28% of the policies do not clearly define these competencies.

The identification of M&E constructs revealed four main patterns: standardization of activities and regulatory focus; systematic monitoring and data quality; evidence-based evaluation; and evaluation*ex-post* . The integration of these constructs varies significantly, with only 28% of policies incorporating all four elements.

As for the structuring of M&E in policies, there was greater maturity in policies for specific health problems, with 90% covering all the constructs, while more recent policies show a tendency towards more comprehensive M&E mechanisms.

The analysis of health policies points to important considerations regarding the future development of M&E mechanisms in the SUS. The need to periodically review older policies to incorporate or update M&E elements, with a view to aligning them with contemporary practices, stands out. This update is essential to ensure that all policies, regardless of their date of creation, have adequate instruments for monitoring and evaluating their results.

Another crucial aspect is the development of specific M&E methodologies for different types of policies, taking into account their particularities and objectives. This methodological customization is especially relevant given the diversity of health policies, which range from promotion and prevention actions to highly complex services. The definition of specific methodologies can contribute to a more precise and contextualized evaluation of the results achieved by each policy.

Strengthening transparency and mechanisms *accountability* appears to be an essential element for M&E in health policies. Increasing access to information on the performance and results of policies not only meets the legal requirements for transparency, but also enables greater social involvement and control. This aspect is particularly relevant in the context of the SUS, where social participation is a fundamental constitutional principle.

These considerations point to the need for a continuous process of improving M&E mechanisms, with a view not only to updating them technically, but also to their effective contribution to improving health policies and, consequently, the population's health care.

It is important to point out that, as with any qualitative analysis, this study has limitations inherent in the subjectivity of the interpretative process. Future research could benefit from peer validation or methodological triangulation to reinforce the robustness of the findings.

Conflict of interest

The authors declare that there is no conflict of interest.

Authors' contribution

Possolli GT contributed to the conception/design of the article, data analysis and interpretation, writing of the article, critical revision of its content and approval of the final version. Lemos ANLE contributed to the conception/design of the article, as well as providing bibliographical references and critically reviewing its content and approving the final version. Alves SMC contributed to the critical revision of its content and approval of the final version.

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